

**TENNESSEE MEDICAL LABORATORY BOARD**  
**POSITION STATEMENT REGARDING SEPARATE LAB LICENSES FOR**  
**POINT OF CARE TESTING SITES ON THE CAMPUS OF A HOSPITAL WITH**  
**A LICENSED MEDICAL LABORATORY**

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**Position Statement**

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**It is the position of the Tennessee Medical Laboratory Board that hospitals with a licensed medical laboratory, and which have one or more other clinical and/or medical laboratory sites located in contiguous buildings on the same hospital campus, may choose to obtain a separate medical laboratory license for one or more of those separate lab sites, so long as each such site first receives Point of Care Testing approval from the Board.**

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**Justification for the Position Statement**

**In stating this position, the Board relies on rule 1200-6-3-.02(1)(c), which permits a hospital to file multiple licensure applications for multiple lab sites:**

Laboratories within a hospital that are located in contiguous buildings on the same campus and under common direction<sup>1</sup> may file a single application or multiple applications for the laboratory sites within the same physical location or street address.

**Purpose of the Position Statement**

**Point of Care Testing (POCT) is, as a matter of law, conducted under the auspices of the hospital's primary licensed medical laboratory (the "main lab"); and therefore under the Board's regulatory oversight and licensure jurisdiction of that main lab. As a consequence, any licensure violation that might occur at a POCT site subjects the license of the hospital's main lab to liability and/or Board discipline. This position statement is intended to highlight a regulatory mechanism by which hospitals that have multiple laboratory locations might better protect the main lab's license from Board discipline that could flow to it from acts or omissions which occur at a separate lab testing site on the same hospital campus.**

**The option of obtaining separate licenses for separate medical laboratory sites within the same hospital campus is an entirely discretionary option which a hospital may choose to pursue in addition to the Point of Care Testing (POCT) process:**

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<sup>1</sup> The Board does not believe that this "common direction" provision forecloses the licensure of a lab site which is located in a contiguous building on the same campus as the hospital's "main lab," but which by regulation cannot be directed by the main lab's director. Instead, in such situations, that separate lab site would, before becoming licensed, have to demonstrate compliance with all laboratory director certification (and other) requirements set forth at Board rule 1200-6-1-.20; just as any other lab licensure applicant would have to do.

**For such a site to be eligible for separate lab licensure, the hospital first must follow the POCT exemption process for that site—as set forth in rule 1200-6-3-.16(1)—and thereby receive POCT approval from the Board for that lab site. Once POCT approval is granted, the hospital may, but is not required to, apply to have that site licensed as a separate medical laboratory.**

**The Board notes that if a hospital in its business discretion chooses to apply for, and is granted, multiple lab licenses for those lab sites which are located in contiguous buildings on the same hospital campus, each such separately licensed lab – regardless of its proximity to the hospital’s main lab or to any other separately licensed lab – is individually required to comply with all requirements set forth in the Medical Laboratory Act, T.C.A. §§ 68-29-101 *et seq.*, and in the Board rules, Tenn. Comp. R. & Regs. 1200-06-01, 1200-06-02, and 1200-06-03.**

*Adopted this the 16th day of April, 2009 by the Tennessee Medical Laboratory Board.*